SUMMARY OF THE ACCREDITATION PROCESS COMMITTEE MEETING NOVEMBER 19, 2002

The Accreditation Process Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Tuesday, November 19, 2002, at 1:30 p.m. Mountain Standard Time (MST) as part of the Eighth NELAC Interim Meeting in Santa Fe, NM. Chairperson Ms. Susan Wyatt of the Minnesota Department of Health led the meeting. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to discuss accreditation issues and receive feedback on the splitting and merging of laboratories.*

AGENDA ITEMS

There are no proposed changes at this time to chapter material. The Accreditation Process Committee has raised the following issues for discussion: splitting and merging of laboratories, due process for appeals from accredited laboratories, and the issue of corrective action reports in response to on-site assessment.

HIGHLIGHTS AND SUBSTANTIVE ISSUES

Splitting and Merging of Laboratories

Ms. Wyatt reviewed the issue, saying that laboratories may want to split or merge for a variety of reasons, and it is costly for labs to be re-accredited. The committee would like to consider the scenario where two laboratories merge together and there is no change in personnel, management, or equipment. One example discussed was a situation of a utility that had two accredited locations and one location moves its personnel and equipment over to the other so that they are a combined laboratory. The two laboratories were required to drop their individual accreditations and re-apply as a new laboratory. Another example offered was a laboratory spread out over four or five buildings that had multiple accreditations, which may want to split into separate laboratory operations. Ms. Wyatt said that it is not the objective of the Accreditation Process Committee to describe every scenario in the NELAC Standards, but the committee does want to give the accrediting authorities (AAs) guidance on how to handle situations.

A participant asked what would be the minimum requirements of two laboratories merging. A committee member responded that the two laboratories should ensure quality assurance records are transferred from one location to another.

A question was raised for Section 4.1.8b (Change of Ownership and/or Location of Laboratory). A committee member, Mr. Ray Frederici reminded the audience that Section 4.1.8b applies specifically to a change in location, and not to merging or splitting of laboratories. One member of the audience suggested that additional language be added to Section 4.1.8b for clarification of this issue and the committee agreed to take this into consideration. Mr. Frederici stated that a new Section 4.6.3 may need to be added to address certain issues.

The committee considered what would be required for laboratories to maintain an accreditation, which might include records of instrumentation, personnel, technology, and expertise of laboratory members. Quality system records supporting a facility are included among the elements that must be transferred to sustain accreditation. The committee informed the audience that their intent was to eliminate obstacles which would prevent an AA from being able to transfer an accreditation.

A participant in the meeting questioned what happens when a laboratory loses personnel. For example, what will happen when a company closes one of its facilities, and the laboratory's personnel and equipment are transferred? Ms. Wyatt reminded the audience that the focus of the meeting was to discuss laboratory mergers; the committee pointed out that this is a situation of an "acquired lab," not of two laboratories merging. The committee members did agree that they may need to adjust the language to address situations where a facility is closed but where a legitimate business entity remains.

Due Process for Appeals from Accredited Laboratories

Referring to the initial example provided by Ms. Wyatt, a participant suggested that a possible course of action for the laboratory was to initiate an appeal. Ms.Wyatt stated that NELAC currently has no appeals process for a laboratory or utility to appeal a decision about an accreditation. Mr. Frederici clarified that NELAC has an appeals process specifically for laboratories where a laboratory's accreditation has been revoked. This process may vary from state to state. He stated that the committee is looking for specific language that would give AA's broad authority to transfer accreditation.

An audience member raised the issue that "re-assessment surveillance" (for relocation of laboratories) is allowed under the International Organization for Standardization (ISO) 17025. The Accreditation Process Committee questioned whether there is the ability for them to capture costs for re-assessment. Chapter 5 of the NELAC Standards contains procedures for handling records for closing of a facility. Ms. Wyatt stated that the committee will consider modifying language in the standards to address this.

Corrective Action Reports in Response to an On-site Assessment

In section 4.1.3g, it was suggested that an editorial change be made to the language. It has been proposed that 4.1.3g should state, "If the laboratory fails to implement and maintain the corrective actions as stated in their corrective action report, accreditation for fields of accreditation, specific methods, or analytes within those fields of accreditation shall be revoked."

Proficiency Testing (PT) Samples

A change has been suggested for Section 4.1.4 (Proficiency Testing Samples). Section 4.1.4b could be misinterpreted to mean that the same PT sample could be used twice. A participant suggested that the language state "...each laboratory seeking or maintaining accreditation shall be required to perform analysis of two sets of PT samples per year in each field of accreditation....".

The committee acknowledged that they also need to check with the Proficiency Testing Committee to make sure that the language is consistent with Chapter 2.

One meeting participant noted that Resource Technology Corporation (RTC) is the only approved laboratory vendor performing PT samples for dioxins. RTC only prepares one PT sample for dioxins each year, but the NELAC Standards require two. Another participant asked whether anyone has approached a laboratory offering to provide two sets of PT samples per year, and questioned whether there is anyone else who offers PT samples for dioxins. Ms. Wyatt said she was not sure if this is an issue for the PT Committee or for the Oversight Board.

FUTURE PLANS

The Accreditation Process Committee will restructure some of the contents of Chapter 4, and review chapter contents to ensure consistency with other chapters.

UNRESOLVED ISSUES

The committee is developing a standard for the merging/splitting of laboratory accreditations. They are currently trying to determine the appropriate location within the NELAC Standards to place this language and information contained in Section 4.8 (Enforcement).

Attachment A

ACTION ITEMS
ACCREDITATION PROCESS COMMITTEE MEETING
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Item No.	Action	Date to be Completed
1.	The committee is going to review and/or develop proposed language changes for the following areas of discussion: mergers and acquisition processes, minimum proficiency testing (PT) sample requirements, corrective action requests, and whether an appeals process (for laboratories) needs to be added to the NELAC Standards.	Ongoing

Attachment B

PARTICIPANTS
ACCREDITATION PROCESS COMMITTEE MEETING
NOVEMBER 19, 2002

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